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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/702,305	11/06/2003	Michael C. Chen	12844-002001	7992
26161	7590	07/10/2006	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			NAVARRO, ALBERT MARK	
			ART UNIT	PAPER NUMBER
			1645	
DATE MAILED: 07/10/2006				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/702,305

Applicant(s)

CHEN ET AL.

Examiner

Mark Navarro

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-79 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-79 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-25, and 55 drawn to a polypeptide which lacks hemolytic activity conjugated to a *S. pneumoniae* capsular polysaccharide, classified in class 530, subclass 350.
- II. Claims 26-44, drawn to a vector encoding a *S. pneumoniae* pneumolysin protein which lacks hemolytic activity, classified in class 435, subclass 320.1.
- III. Claims 45-49, drawn to a vector encoding a *S. pneumoniae* autolysin protein, classified in class 435, subclass 320.1.
- IV. Claims 50-54, drawn to a vector encoding a *S. pneumoniae* pneumococcal surface protein A which lacks hemolytic activity, classified in class 435, subclass 320.1.
- V. Claims 56-64, drawn to methods of inducing an immune response with a peptide, classified in class 424, subclass 184.1.
- VI. Claims 65-66, drawn to methods of inducing an immune response with a vector encoding a *S. pneumoniae* pneumolysin protein which lacks hemolytic activity, classified in class 514, subclass 44.
- VII. Claims 67-68, drawn to methods of inducing an immune response with a vector encoding a *S. pneumoniae* autolysin protein, classified in class 514, subclass 44.

- VIII. Claims 69-70, drawn to methods of inducing an immune response with a vector encoding a *S. pneumoniae* pneumococcal surface protein A, classified in class 514, subclass 44.
- IX. Claims 71-73, drawn to methods of inducing an immune response with a vector encoding a *S. pneumoniae* pneumolysin protein, classified in class 514, subclass 44.
- X. Claims 74-75, drawn to a polypeptide which lacks hemolytic activity conjugated to a non-*S. pneumoniae* capsular polysaccharide, classified in class 530, subclass 350.
- XI. Claims 76-77, drawn to a method of inducing an immune response with a polypeptide which lacks hemolytic activity conjugated to a non-*S. pneumoniae* capsular polysaccharide, classified in class 424, subclass 184.1.
- XII. Claim 78, drawn to an antibody, classified in class 530, subclass 387.1.
- XIII. Claim 79, drawn to a method of prevention with an antibody, classified in class 424, subclass 130.1.

The inventions are distinct, each from the other because of the following reasons:

Invention I, drawn to a protein, and Inventions II-IV, drawn to a DNA molecule are distinct since they are products with different structure and biological properties. The protein is made of amino acids whereas the nucleic acid consists of nucleotides. Further methods known in the art used to make the polypeptide require different reagents and parameters from the methods of making the nucleic acid encoding the

protein and the method of making the polypeptide does not require the nucleic acid. For instance, the protein can be made by Merrifield chemical synthesis or affinity chromatography. Furthermore, each of Inventions II-IV are distinct since they each represent a unique molecule with a distinct structure and function.

Invention XII, drawn to an antibody is distinct from Inventions I-XI and XIII, since it has an inherent affinity, avidity, and specificity that DNA or a simple protein is not capable of expressing.

Inventions II-IV and V-IX & XI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the protein/DNA molecule can be administered in vivo as claimed, or alternatively incorporated into an in vitro assay to screen for the presence of target molecules.

Inventions I and X are directed to related conjugates. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the conjugates are mutually exclusive, conjugated to a *S. pneumoniae* capsular polysaccharide or alternatively to a non-*S. pneumoniae* capsular polysaccharide.

Inventions XII and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the antibody can be administered in vivo as claimed, or alternatively incorporated into an in vitro assay to screen for the presence of the protein.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions

unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1645

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Mark Navarro
Primary Examiner
July 2, 2006